



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

FEB 18 2005

Food and Drug Administration
College Park, MD 20740

Robert C. Brown, PhD, MPH
Senior Group manager
Nutrition and Regulatory Affairs
Frito-Lay, Inc.
P.O. Box 660634
Dallas, TX 75266-6034

Re: Notification for a health claim based on an authoritative statement

Dear Dr. Brown:

This letter acknowledges receipt on February 4, by the Food and Drug Administration (FDA) of the health claim notification you submitted pursuant to Section 403(r)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)(3)). The notification is informing FDA of a health claim characterizing the relationship between the consumption of whole grains and reduced risk of coronary heart disease. The health claim is based on an authoritative statement from the National Academy of Sciences report entitled "Diet and Health: Implications for Reducing Chronic Disease Risk."

The notification is undergoing FDA review. In accordance with Section 403(r)(3)(C) of the act, within 120 days (ending on June 4, 2005) of receipt of your health claim notification, you will be informed by FDA if the notification does not comply with Section 403(r)(3) of the act. A lack of action by FDA within the 120-day period will deem the proposed health claim approved and will allow a food with a label containing the claims to be introduced into interstate commerce.

If you have any questions concerning this notification, please feel free to contact me at (301) 436-2031 or julie.moss@fda.gov.

Sincerely,

for Julie Moss
Consumer Safety Officer
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Safety
and Applied Nutrition

200502-0211

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